



RON CHAPMAN, MD, MPH
Director & State Health Officer

State of California—Health and Human Services Agency
California Department of Public Health



EDMUND G. BROWN, JR.
Governor

December 16, 2013

AFL 13-32
(Supersedes AFL 12-26)

TO: All Clinics
Ambulatory Surgery Centers

SUBJECT: Adverse Event Reporting for Accredited Outpatient Settings

AUTHORITY: Senate Bill (SB) 304 (Chapter 515, Statutes of 2013)
Business & Professions Code (BPC) Sections 2216.3, 2216.4.
Health & Safety Code (HSC) Sections 1248.1, 1248.15, 1279.1,
1280.4.

This All Facilities Letter (AFL) serves as notification of changes to adverse event reporting for accredited outpatient settings which take effect January 1, 2014.

Prior legislation amended HSC Section 1248.15 to require all outpatient settings to report adverse events to the California Department of Public Health (CDPH) and made outpatient settings subject to civil penalties for failure to report within specified timeframes.

An “outpatient setting” is defined in HSC Section 1248 as “any facility, clinic, unlicensed clinic, center, office or other setting that is not part of a general acute care facility, as defined in Section 1250, and where anesthesia, except local anesthesia, or peripheral nerve blocks, or both, is used in compliance with the community standard of practice, in doses that, when administered have the probability of placing a patient at risk for loss of the patient’s life-preserving protective reflexes.”

Recently enacted legislation (SB 304, Chapter 515, Statutes of 2013) added Sections 2216.3 and 2216.4 to the BPC clarifying that only outpatient settings that are accredited by a Medical Board of California (MBC) approved accrediting agency be required to report adverse events to the MBC (within the same timeframes as provided by HSC 1279.1), rather than to the CDPH, and that the MBC may assess the accredited outpatient setting a civil penalty if it fails to report an adverse event.

The information in this AFL is a brief summary of SB 304’s changes to adverse event reporting requirements. Facilities are responsible for following all applicable laws.

AFL 13-32
December 16, 2013
Page 2

CDPH's failure to expressly notify facilities of legislative changes does not relieve facilities of their responsibility for following all laws and for being aware of all legislative changes. Facilities should refer to the full text of BPC Sections 2216.3 and 2216.4 to ensure compliance.

Sincerely,

Original signed by Debby Rogers

Debby Rogers, RN, MS, FAEN
Deputy Director
Center for Health Care Quality